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8 UNITED STATES DISTRICT COURT
9 SOUTHERN DISTRICT OF CALIFORNIA
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11 DINA ANDREN, SIDNEY BLUDMAN,
12 VIRGINIA CIOFFI, BERNARD FALK,
13 JEANETTE KERZNER-GREEN,
14 CAROL MONTALBANO, and
15 DONALD RIGOT, individually, and on
behalf of other members of the general
public similarly situated, ,

16 Plaintiff,

17 v.

18 ALERE, INC., a Delaware corporation,
19 ALERE HOME MONITORING, INC., a
20 Delaware corporation, ALERE SAN
DIEGO, INCA., a Delaware corporation,,
21

Defendant.

Case No.: 16cv1255-GPC(AGS)

**ORDER DENYING PLAINTIFFS'
MOTION FOR
RECONSIDERATION**

[Dkt. No. 151.]

22
23 Before the Court is Plaintiffs' motion for reconsideration of the Court's order
24 denying class certification filed on December, 2017, Dkt. No. 140. (Dkt. No. 151.)
25 Defendants filed an opposition. (Dkt. Nos. 179.) Plaintiffs filed a reply. (Dkt. No. 183.)
26 After a review of briefs, supporting documentation and applicable law, the Court
27 DENIES Plaintiffs' motion for reconsideration.

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Background

The original complaint was filed on May 26, 2016. (Dkt. No. 1.) After the Court granted Defendants' motion to dismiss with leave to amend, (Dkt. No. 19), on October 3, 2016, Plaintiffs Dina Andren ("Andren"), Sidney Bludman ("Bludman"), Virginia Cioffi ("Cioffi"), Bernard Falk ("Falk"), Jeanette Kerzner-Green ("Kerzner-Green"), Carol Montalbano ("Montalbano") and Donald Rigot ("Rigot") (collectively "Plaintiffs") filed the operative purported first amended class action complaint ("FAC") against Defendants Alere, Inc., Alere Home Monitoring, Inc., ("AHM"), and Alere San Diego, Inc. ("Alere SD") (collectively "Defendants" or "Alere") for unlawfully, deceptively and misleadingly engaging in the advertising, marketing and sale of the INRatio products which include "INRatio PT/INR Monitors," "INRatio PT/INR Test Strips," "INRatio2 PT/INR Monitors" and "INRatio2 PT/INR Test Strips" (collectively, "INRatio Products"). (Dkt. No. 21, FAC.) The FAC alleges sixteen causes of action for violations of (1) California's Consumer Legal Remedies Act, ("CLRA"), Cal. Civil Code §§ 1750 *et seq.*; (2) California's Unfair Competition Law, ("UCL"), Cal. Bus. & Prof. Code §§ 17200 *et seq.*; (3) fraud; (4) unjust enrichment; (5) Colorado Consumer Protection Act, Colo. Rev. Stat. §§ 6-1-101 *et seq.*; (6) breach of the implied warranty of merchantability, Colo. Rev. Stat. § 4-2-314; (7) Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. §§ 501.201, *et seq.*; (8) breach of the implied warranty of merchantability, Fla. Stat. §§ 672.314, *et seq.*; (9) Georgia Fair Business Practices Act, Ga. Code Ann. §§ 10-1-390, *et seq.*; (10) Georgia Uniform Deceptive Trade Practices Act, Ga. Code Ann. §§ 10-1-370, *et seq.*; (11) Maryland Consumer Protection Act, Md. Code Com. Law §§ 13-101, *et seq.*; (12) breach of the implied warranty of merchantability under Md. Code Com. Law § 2-314; (13) New York General Business Law, N.Y. Gen. Bus. Law § 349; (14) New York General Business Law, N.Y. Gen. Bus. Law § 350; (15) Pennsylvania Unfair Trade

Practices and Consumer Protection Law, Pa. Stat. Ann. §§ 201-1, *et seq.*; and (16) breach of the implied warranty of merchantability, 13 Pa. Stat. Ann. § 2314.¹ (*Id.*)

Plaintiffs filed a motion for class certification on June 21, 2017. (Dkt. No. 75.) After the motion was fully briefed, including a sur-reply, the Court held a hearing on September 22, 2017 and then ordered supplemental briefing on the issue of claim splitting. (Dkt. Nos. 122, 125.) The parties filed supplemental briefing on October 13, 2017 and October 20, 2017. (Dkt. Nos. 128, 129.) On December 20, 2017, the Court denied Plaintiffs' motion for class certification. (Dkt. No. 140.)

On January 31, 2018, Plaintiffs filed a motion for reconsideration of the class certification order. (Dkt. No. 151.) Defendants filed an opposition on March 16, 2018. (Dkt. No. 179.) Plaintiffs filed their reply on March 30, 2018. (Dkt. No. 183.) With leave of Court, Defendants filed a sur-reply on April 18, 2018. (Dkt. No. 203.)

Discussion

A. Legal Standard

Plaintiffs move for reconsideration under Federal Rule of Civil Procedure ("Rule") 60(b). Sch. Dist. No. 1J, Multnomah County, Or. v. AcandS, Inc., 5 F.3d 1255, 1262 (9th Cir. 1993).² Defendants oppose arguing that Rule 60(b) does not apply and Plaintiffs' motion is untimely under these standards.

While the motion is labeled a motion for reconsideration, the Court recognizes that "[a]n order that grants or denies class certification may be altered or amended before final judgment." Fed. R. Civ. P. 23(c)(1)(C); Rodriguez v. West Publ'g Corp., 563 F.3d 948, 966 (9th Cir. 2009) ("A district court may decertify a class at any time.") "Even after a

¹ On January 17, 2017, the Court granted Defendants' motion to strike paragraph 74 of the FAC and denied Defendants' request to strike the remaining paragraphs of 75-80. (Dkt. No. 41.)

² A motion for reconsideration is "appropriate if the district court (1) is presented with newly discovered evidence; (2) clear error or the initial decision was manifestly unjust, or (3) if there is an intervening change in controlling law." Sch. Dist. No. 1J, Multnomah County, Or., 5 F.3d at 1263.

1 certification order is entered, the judge remains free to modify it in the light of
2 subsequent developments in the litigation.” Gen. Tel. Co. of the Sw. v. Falcon, 457 U.S.
3 147, 160 (1982). Because the Court has discretion to modify an order on class
4 certification prior to judgment, the Court considers Plaintiffs’ motion under Rule 23 and
5 not under the parameters of a motion for reconsideration.

6 In the Court’s order, it denied certification of a nationwide class and also of the six
7 sub-class states. (Dkt. No. 140 at 11.) In their motion, Plaintiffs seek the Court’s
8 reconsideration of the class certification denial of the six sub-class states. In the FAC,
9 Plaintiffs seek to certify six sub-classes States represented by them: a Colorado, Florida,
10 Georgia, Maryland, New York and Pennsylvania Sub-Class to include, “All residents of
11 [each Plaintiffs’ respective home State] who, during the period January 1, 2009 through
12 the present, purchased, rented or otherwise paid for the use of the INRatio products
13 manufactured, marketed, sold or distributed by Defendants.” (See Dkt. No. 21, FAC ¶
14 148.) They argue that newly discovered facts not available at the time of class
15 certification demonstrate that predominance has been satisfied as to the individual state
16 sub-classes on the learned intermediary doctrine, statute of limitations and damages.³

17 **B. Predominance**

18 Rule 23(b)(3) requires a court to find that “the question of law or fact common to
19 class members predominate over any questions affecting only individual members.” Fed.
20 R. Civ. P. 23(b)(3). Plaintiff “must affirmatively demonstrate compliance” with Rule 23
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23 ³ The alleged new facts concern newly produced internal documents by Alere that allegedly show that it
24 was discussing defects or errors with a software algorithm since March 2012. Based on these
25 documents, Plaintiffs claim that Alere fraudulently concealed the products’ defect and it was not until
26 July 11, 2016 when the recall was issued that they discovered the devices could not be safely used.
27 (Dkt. No. 193-1 at 9 (UNDER SEAL).) In response, Alere disputes Plaintiffs’ interpretation of these
28 documents explaining that an algorithm error avoids the possibility of a discrepant result by reporting an
error code instead of a potentially erroneous INR. (Dkt. No. 179 at 21 n.8.) The documents submitted
by Plaintiffs to support their legal theory is not easily understandable to a layperson and they fail to
provide sufficient explanation that the software algorithm, which appears to be raised for the first time
with the Court, is the alleged defect in the INRatio Products.

1 and must satisfy Rule 23(b)(3) with “evidentiary proof.” Comcast Corp. v. Behrend, 569
2 U.S. 27, 33 (2013) (Rule 23(b)(3)’s predominance standard is even more demanding than
3 Rule 23(a)). The Court is required to perform a “rigorous analysis,” which may require it
4 “to probe behind the pleadings before coming to rest on the certification question.”
5 Dukes, 564 U.S. 338, 350-51 (2011) “[T]he merits of the class members’ substantive
6 claims are often highly relevant when determining whether to certify a class. More
7 importantly, it is not correct to say a district court may consider the merits to the extent
8 that they overlap with class certification issues; rather, a district court must consider the
9 merits if they overlap with Rule 23(a) requirements.” Ellis v. Costco Wholesale Corp.,
10 657 F.3d 970, 981 (9th Cir. 2011).

11 The central Rule 23(b)(3) inquiry is whether “the proposed classes are sufficiently
12 cohesive to warrant adjudication by representation.” Amchem Prods., Inc. v. Windsor,
13 521 U.S. 591, 594 (1997). If common questions “present a significant aspect of the case
14 and they can be resolved for all members of the class in a single adjudication,” then
15 “there is clear justification for handling the dispute on a representative rather than on an
16 individual basis,” and the predominance test is satisfied. Hanlon v. Chrysler Corp., 150
17 F.3d 1011, 1022 (9th Cir. 1998). “[I]f the main issues in a case require the separate
18 adjudication of each class member's individual claim or defense, [however,] a Rule
19 23(b)(3) action would be inappropriate.” Zinser v. Accufix Research Institute, Inc., 253
20 F.3d 1180, 1190 (9th Cir. 2001) (quoting 7A Charles Alan Wright, Arthur R. Miller &
21 Mary Kay Kane, *Federal Practice and Procedure: Civil 2d* § 1778, at 535–39 (1986)).

22 **i. Learned Intermediary Doctrine**

23 In the Court’s prior order, it concluded that Plaintiffs had not demonstrated
24 predominance under Rule 23(b)(3) because Plaintiffs failed to demonstrate that the
25 defense of learned intermediary was amenable to class wide treatment as it applies to
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1 Plaintiffs' home states' consumer protection laws. (Dkt. No. 140 at 42-43.⁴) While
2 Plaintiffs alleged in the FAC and at oral argument that Alere never warned any healthcare
3 provider about the alleged defect, they failed to directly address the issue with legal or
4 factual analysis during briefing on class certification.

5 In their instant motion, Plaintiffs argue that common issues predominate on the
6 learned intermediary doctrine because Alere failed to warn any physicians, and therefore
7 the issue is subject to common proof.⁵ Plaintiffs assert for the first time that the learned
8 intermediary doctrine is recognized in the six sub-class states. Responding, Defendants
9 argue Plaintiffs fail to address the full scope of a learned intermediary analysis which not
10 only requires a showing that the warnings were inadequate but also to demonstrate the
11 inadequate or lack of warnings were the proximate cause of Plaintiffs' injuries.
12 Demonstrating proximate causation requires an array of individual inquiries about
13 Plaintiffs' prescribing physicians. In reply, for the first time, Plaintiffs argue that the
14 learned intermediary doctrine does not apply because their case concerns a design defect
15 that prevented the product from working as intended and not a failure to warn. Next, they
16 argue that because Plaintiffs do not allege physical injuries and only suffered economic
17 injuries, the doctrine has no application where the alleged injuries are solely economic
18 based on the purchase price of the device. Lastly, they argue that because the INRatio
19 monitor is a user-operated diagnostic monitor that does not directly affect the patient's
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22 ⁴ Page numbers are based on the CM/ECF pagination.

23 ⁵ The parties dispute who has the burden to prove the application or non-application of the learned
24 intermediary doctrine. Plaintiffs, relying on Saavedra v. Eli Lilly & Co., No. 12cv9366-SVW-MAN,
25 2013WL 6345442, at *3 (C.D. Cal. Feb. 26, 2013), a case from the District Court for the Central District
26 of California stated that the manufacturer must demonstrate that the prescribing physicians were
27 adequately warned. Defendants argue that Plaintiffs bear the burden that Alere's warnings were
28 inadequate citing Dietz v. Smithkline Beecham Corp., 598 F.3d 812, 8 (11th Cir. 2010) (applying
Georgia law stating that plaintiff has the burden to show that the defendant had a duty to warn). (Dkt.
No. 179 at 26.) Notwithstanding who has the initial burden, ultimately, Plaintiffs have the burden to
prove that common questions of law or fact will predominate over any individual inquiries on the
learned intermediary doctrine. See Fed. R. Civ. P. 23(b)(3).

1 physiology, the doctrine does not apply to medical devices which requires the patient to
2 use the devices themselves.

3 Restatement (Third) of Torts concerning Liability of Commercial Seller or
4 Distributor for Harm Caused by Defective Prescription Drugs and Medical Devices
5 provides,

6 (d) A prescription drug or medical device is not reasonably safe due to
7 inadequate instructions or warnings if reasonable instructions or warnings
8 regarding foreseeable risks of harm are not provided to:

9 (1) prescribing and other health-care providers who are in a position to
reduce the risks of harm in accordance with the instructions or warnings; . .

10 . .
Restatement (Third) Torts, Prod. Liab. § 6(d)(1) (1998).

11 It is now not disputed that the learned intermediary doctrine applies to the six
12 subclass states based on a failure to warn.⁶ See Beale v. Biomet, Inc., 492 F. Supp. 2d
13 1360 (S.D. Fla. 2007); Porter v. Eli Lilly and Co., No. 16cv1297-JOF, 2008 WL 544739,
14 at *6 (N.D. Ga. Feb. 25, 2008) (noting that the doctrine is well established in state tort
15 law as it applies in forty-four jurisdictions, including Georgia.); Martin v. Hacker, 185
16 A.D. 2d 553, 554–55 (N.Y. App. Div. 1992); Doe v. American Nat’l Red Cross, 866 F.
17 Supp. 242, 248 (D. Md. 1994); Taurino v. Ellen, 579 A.2d 925, 927 (Pa. Super. Ct.
18 1990); Caveny v. CIBA–GEIGY Corp., 818 F. Supp. 1404, 1406 (D. Colo. 1992) (“It is
19 the responsibility of the physician as a learned intermediary to assess the risks and
20 benefits of a particular course of treatment.”).

21 As described by one district court concerning the rationale behind the doctrine,
22 “[a]s a medical expert, the prescribing physician can take into account the propensities of
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25 ⁶ It does not appear that the parties dispute that the learned intermediary doctrine applies to medical
26 device cases in failure to warn cases. See Ellis v. C.R. Bard, Inc., 311 F.3d 1272, 1280 (11th Cir. 2002)
27 (applying Georgia law); O’Connell v. Biomet, Inc., 250 P.3d 1278, 1281-82 (Colo. Ct. Appeal 2010)
28 (learned intermediary doctrine applies to failure to warn claims for a medical device); Beale v. Biomet, Inc., 492 F.Supp.2d 1360, 1367–68 (S.D. Fla. 2007) (collecting cases) (applying Florida law); Pumphrey v. C.R. Bard, Inc., 906 F. Supp. 334, 337 (N.D.W. Va. 1995) (“the learned intermediary doctrine[] is nearly universal”).

1 the drug, as well as the susceptibilities of his patient. His is the task of weighing the
2 benefits of any medication against its potential dangers. The choice he makes is an
3 informed one, an individualized medical judgment bottomed on a knowledge of both
4 patient and palliative.” Porter, 2008 WL 544739, at *6 (citation omitted) (applying
5 Georgia law); O’Connell v. Biomet, Inc., 250 P.3d 1278, 1281-81 (Colo. Ct. Appeal.
6 2010) (“we are persuaded that the learned intermediary doctrine should apply to failure to
7 warn claims in the context of a medical device installed operatively when it is available
8 only to physicians and obtained by prescription, and the doctor is in a position to reduce
9 the risks of harm in accordance with the instructions or warnings.”).

10 To prevail on a cause of action based on a failure to warn a learned intermediary, a
11 plaintiff must prove that the warning to the physician was inadequate, the inadequate
12 warning caused his or her injury and he or she suffered an injury from the device. See
13 Hoffmann-La Roche Inc., 27 So. 3d 75, 77 (Fla. Ct. App. 2009) (appellee failed to show
14 that the inadequate warning was the proximate cause of his injury because physician
15 testified that even if the warning label contained all the warnings, he still would have
16 prescribed the medication for appellee); Demmler v. SmithKline Beecham Corp., 671 A.
17 2d 1151, 1155 (Pa. Super. Ct. Feb. 14, 1996) (noting that even if plaintiff has established
18 a failure to warn, a plaintiff must also demonstrate proximate cause by “showing that had
19 defendant issued a proper warning to the learned intermediary, he would have altered his
20 behavior and the injury would have been avoided.”) (citation omitted); Porter, 2008 WL
21 544739, at *9-11 (N.D. Ga. 2008); Ames v. Apothecon, Inc., 431 F. Supp. 2d 566, (D.
22 Md. 2006) (plaintiff must show that the inadequate warning caused the injury stating “a
23 product defect claim based on insufficient warnings cannot survive summary judgment if
24 stronger warnings would not have altered the conduct of the prescribing physician.”);
25 Wollam v. Wright Medical Grp., Inc., No. 10cv3104-DME-BNB, 2012 WL 4510695, at
26 *6 (D. Colo. Sept. 30, 2012) (“Plaintiffs have not submitted any evidence suggesting that
27 any failure to warn or inadequacy of the warnings [the defendant] gave was the proximate
28 cause of [the plaintiff’s] harm” because doctor testified that he never read the

1 instructions); Mulhall v. Hannafin, 45 A.D. 3d 282, 287 (N.Y. App. Div. 2007) (“Under
2 well settled law, to prove proximate cause, a plaintiff has the obligation to adduce proof
3 that had a warning been provided, she would have read the warning and heeded it.”). “In
4 the event that a warning is inadequate, proximate cause is not presumed.” Demmler, 671
5 A.2d at 1155. Here, Plaintiffs do not dispute that individual inquiries will be necessary to
6 determine proximate cause. Instead, they change position in their reply and now argue
7 that the learned intermediary doctrine does not even apply in their case.

8 In each sub-class state, a learned intermediary doctrine analysis requires more than
9 just demonstrating that warnings to healthcare providers were inadequate or that there
10 was a failure to make any warnings, it also requires demonstrating proximate cause. The
11 cases above reveal that a proximate cause determination will ultimately lead to individual
12 inquiries into each doctor’s experience with the product. Saavedra, a Central District of
13 California case, relied on by Plaintiffs, stated that even if the warnings were inadequate,
14 plaintiffs would still be required to prove the inadequate warning caused their injuries.
15 Saavedra v. Eli Lilly & Co., No. 12cv9366-SVW-MAN, 2013 WL 3148923, at *4 (C.D.
16 Cal. June 13, 2013). The court stated that such a question will require that fact-finder to
17 engage in a series of individualized assessments such as “1) if the individual plaintiff had
18 known about the severity, duration, and extent of [the prescription drug’s] withdrawal,
19 would she or he still have taken the medication?; 2) if the individual plaintiff’s physician
20 had known about the relevant side-effects, would the physician still have recommended
21 and prescribed [the prescription drug]?; 3) did the individual plaintiff’s physician know
22 of the side effects from a source other than the warning label, and prescribe [the
23 prescription drug] even with this knowledge?” Id. at *4. The court concluded,
24 “[a]lthough the question of whether or not the warnings given to doctors, and consumers,
25 were inadequate or misleading may be capable of resolution on a class-wide basis, the
26 question of whether or not, had the warnings been adequate, each plaintiff would not
27 have taken [the prescription drug] are not.” Id.

1 It is not disputed that the failure to give any warnings to the health care providers
2 can be demonstrated by common proof; however, Plaintiffs have fail to demonstrate that
3 the issue of whether the INRatio Products proximately caused Plaintiffs' injuries is
4 subject to common proof. Plaintiffs have also not provided a case where class
5 certification was granted involving the learned intermediary doctrine.

6 In reply, for the first time, Plaintiffs raise new arguments asserting that a full
7 learned intermediary analysis is not required because the doctrine does not apply to a
8 design defect case, does not apply to plaintiffs seeking economic injuries, and does not
9 apply to a product that is user-operated.

10 First, as to the claim that their case involves a design defect, the Court notes that
11 there are no allegations of a design defect in the FAC. (See Dkt. No. 21, FAC.) In fact,
12 the Court characterized Plaintiffs' misrepresentations and omissions claims as based on a
13 failure to warn. (Dkt. No. 19 at 17.) Moreover, Plaintiffs do not cite any cases from
14 Plaintiffs' home states that hold that the learned intermediary doctrine does not apply to a
15 design defect claim. The Court does not find Plaintiffs' argument supported. Next,
16 Plaintiffs fail to present any legal authority that the learned intermediary doctrine only
17 applies to physical injuries, not economic injuries. Defendants respond by citing to
18 Saavedra, where the court applied the learned intermediary doctrine to four states'
19 consumer protection law, including New York even though putative class members did
20 not seek damages for personal injuries. See Saavedra, Eli Lilly & Co., No. 12cv9366-
21 SVW(MANX), 2014 WL 7338930, at *3 (C.D. Cal. Dec. 18, 2014) ("At the heart of
22 Plaintiffs' case lies their novel theory of damages. Plaintiffs do not seek damages for
23 personal injuries."). Lastly, Plaintiffs argue that because the INRatio is a user-operated
24 device, the doctrine does not apply. Plaintiffs cite to a general proposition from a district
25 court case in the Western District of Pennsylvania that the failure to warn applies to the
26 "intended user" and a California appellate case. In sur-reply, Defendants argue that
27 Plaintiffs fail to present any authority for the argument and cites to two cases applying
28 Georgia law that applied the doctrine to user-operated devices. Ellis v. C.R. Bard, Inc.,

311 F.3d 1272, 1280-81 (11th Cir. 2002) (applying learned intermediary doctrine to pain control pump prescribed by physician but operated by patient); Edwards-Astin v. Medtronic Minimed, Inc., Civil No. 08cv103-CAP, 2008 WL 11319723, at *1 (N.D. Ga. June 3, 2008) (same). The Court does not find that Plaintiffs’ new alternative theory that the learned intermediary doctrine does not apply in this case is supported or is persuasive.

Accordingly, the Court concludes Plaintiffs have not satisfied their burden to affirmatively demonstrate predominance as to the learned intermediary doctrine. See Comcast, 569 U.S. at 33. The Court DENIES Plaintiffs’ motion for reconsideration on this issue.

ii. Comcast Damages

In the Court’s order, it also concluded that Plaintiffs had not demonstrated that their damages model satisfies Comcast to satisfy predominance. (Dkt. No. 140 at 47.) Both parties improperly relied on California law to address Plaintiffs’ full refund damages model theory and failed to address whether the full refund model is consistent with their theories of liability under Colorado, Florida, Georgia, Maryland, New York and Pennsylvania law.

Plaintiffs must present a damages model that is consistent with their liability case, and the court “must conduct a rigorous analysis to determine whether that is so.” Comcast Corp., 133 S. Ct. at 1433 (2013) (internal quotation marks omitted). Plaintiffs “must be able to show that their damages stemmed from the defendant’s actions that created the legal liability.” Leyva v. Medline Industries, Inc., 716 F.3d 510, 514 (9th Cir. 2013). While a plaintiff must present the likely method for determining class damages, “it is not necessary to show that [this] method will work with certainty at this time.” Chavez v. Blue Sky Natural Beverage Co., 268 F.R.D. 365, 379 (N.D. Cal. 2010).

Plaintiffs argue that their theory of liability is simple, “Alere engaged in a pattern and practice of deceptive and dishonest marketing, causing consumers to pay money for worthless products that were ultimately recalled. Because Plaintiffs allege the products provided no value, a full refund is consistent with Plaintiffs’ theory.” (Dkt. No. 151-1 at

18.) They also argue that Comcast “simply requires” that they connect their damages to their theories of liability without having to address the issue on a state by state basis and cite to cases. (Id.) Plaintiffs claim that the cases they cite to support a full refund model in a class action “decline to analyze the plaintiff’s damages models, and their adherence to the standard defined in Comcast, on a state-by-state basis.” (Dkt. No. 151-1 at 18.)

Defendants argue that Plaintiffs fail to demonstrate that a full refund is recoverable but only cite to cases applying California law. They further contend that Plaintiffs have failed to provide any evidence that the INRatio product was entirely worthless to every class member and only rely on their expert’s declaration that no consumer would have purchased the product had they known about the potential for discrepant results and therefore, the product had no value to them.⁷

The Court disagrees with Plaintiffs’ contention that a state by state analysis is not necessary and conclude that their cited cases are also not supportive. For example, in Rikos v. Procter & Gamble Co., 799 F.3d 497, 512-17 (6th Cir. 2015), the court conducted an analysis of the different states’ consumer protection statutes prior to determining whether Comcast was met. Likewise the Court in Makaeff v. Trump Univ., 309 F.R.D. 631 (2015) conducted an analysis of California’s three consumer protection statutes, California Unfair Competition Law (“UCL”), California False Advertising Law (“FAL”), and California Consumer Legal Remedies Act (“CLRA”) noting that these statutes provide for restitution which seeks to put the plaintiff back to the status quo prior to the misrepresentation. Id. at 636. The Court then turned to Florida and New York law, noting that the three statutes at issue, the Florida Misleading Advertising Law, the Florida Deceptive and Unfair Trade Practices Act (“FDUTPA”) and the New York deceptive practices statute, N.Y. Gen. Bus. Law § 349, provide for recovery of actual

⁷ Defendants also argue that initially Plaintiffs sought a refund of the customer’s purchase price but now seeks a damages model based on Alere’s sales revenue. In reply, Plaintiff disagrees and argue that they still seek damages based on the customer’s purchase price. They explain that their expert factored in Alere’s revenues into his damages model explaining that damage calculations need not be exact.

1 damages, not restitution damages. Id. at 641-42. After conducting an analysis of these
2 state laws and the available damage provided by the statutes, the Court concluded that the
3 plaintiffs' damages model was aligned with the theory of liability under California, New
4 York and Florida law. Id. at 640, 642.

5 Plaintiffs also cite to Lambert v. Nutraceutical Corp., 870 F.3d 1170, 1182 (9th
6 Cir. 2017) where the Ninth Circuit reversed the district court's decertification order. The
7 Ninth Circuit analyzed California's damages calculations under the theories of liability
8 alleged, the UCL, FAL, and CLRA, to determine class wide damages calculations noting
9 that damages calculation under these statutes were forgiving. Id. at 1183. In concluding
10 that the full refund model applied, it concluded that plaintiff had presented evidence that
11 the product was valueless and was amenable to full refund treatment and conclude that
12 the full refund model is consistent with plaintiff's theory of liability. Id. at 1183-84.

13 In another case, Williams v. Jet One Jets, Inc., 755 F. Supp. 2d 1281, 1289 (N.D.
14 Ga. 2010), not a class action case, Plaintiffs cite the language, "measure of damages to be
15 applied for an FBPA violation is that of actual injury suffered." However, the next
16 sentence states, "Actual damages' for purposes of the FBPA, means relief other than the
17 refund of the purchase price and restitution." Id. (citation omitted). Plaintiffs provide no
18 analysis as to whether actual damages under Georgia's FBPA allow for a full refund
19 recovery of the purchase price.

20 Finally, in Chapman v. Tristar Prod., Inc., No. 16cv1114, 2017 WL 1433259 (N.D.
21 Ohio Apr. 24, 2017), the plaintiffs sought a breach of implied warranty class consisting
22 of thirty states. Id. at 9. However, the court only certified a Colorado class for implied
23 warranty of merchantability because the other states' laws would not satisfy
24 predominance. Id. Interestingly, the court declined to certify a Pennsylvania implied
25 warranty of merchantability class. Id. at 10. The court noted that each state defines
26 "merchantability" under UCC § 2-314 differently and "whether an alleged defect meets
27 that threshold." Id. at 9 ("§ 2-314's application differs across states because fifty state
28 legislatures and judiciaries have differently enacted and interpreted the provision.")

Moreover, while some states define implied warranty as a contract, other states recognize it as a tort and this affects whether a plaintiff is entitled to economic losses. Id. The court also denied certification of a Pennsylvania UTPCPL class. Id. at 13. This case highlights the distinctions between each state law.

Similarly, Plaintiffs seek an implied warranty of merchantability class under Colorado, Florida, Maryland and Pennsylvania statutes because they all adopted § 2-314 of the UCC implying that these states apply the same standard. (Dkt. No. 111 at 29 (under SEAL).) However, as noted in Chapman, each state interprets § 2-314 differently. Plaintiffs have failed to specifically explain how each of these states' interpretation of the § 2-314 are consistent or how they differ.

Here, Plaintiffs summarily conclude that because there are cases that have held that the full-refund damages model satisfies Comcast under certain of their states' consumer protection law,⁸ then Comcast is necessarily met. However, Comcast demands a "rigorous analysis" and is not satisfied by merely arguing that courts in some of the six states allow for a full refund model. Plaintiffs have failed to specifically demonstrate that each of the six sub-class states' consumer protection statute and claims for implied breach of warranty in four sub-class states are connected to their theory of damages or that these state law causes of action damages provide for a full refund recovery. Thus, the Court DENIES Plaintiffs' motion for reconsideration on the issue of Comcast damages.

iii. Statute of Limitations

In denying class certification, the Court concluded that the predominance factor had not been met as it concerned the statute of limitations in Colorado, Florida, Georgia,

⁸ Plaintiffs provide cases that have applied the full refund recovery damages under Florida's FDUTPA, New York's General Business Law § 349, and Colorado's implied breach of warranty but have not provided cases that have applied full refund recovery on all their causes of action in all of their home states

1 Maryland, New York and Pennsylvania because both parties failed to adequately address
2 the issue and cited only to California law. (Dkt. No. 140 at 45-46.)

3 In the motion for reconsideration, Plaintiffs argue that the class claims are not
4 barred by the statute of limitations as Plaintiffs' home states recognize equitable tolling
5 of the statute of limitations. Moreover they contend that the discovery rule is recognized
6 in Colorado, Florida, Maryland and Pennsylvania and Georgia codified its own discovery
7 rule under Ga. Code. Ann. § 10-1-401. Plaintiffs argue that it was not until July 11,
8 2016, when they received the recall notices, when they discovered that the INRatio
9 Products could not be safely used. Therefore, their claims are not barred by the statute of
10 limitations. Defendants respond that individual questions as to the applicability of the
11 statute of limitations prevent certification.

12 As with the learned intermediary and Comcast damages issues, Plaintiffs fail to
13 sufficiently demonstrate that common issues of law or fact will predominate over
14 individual inquiries on the statute of limitations. In their moving brief, Plaintiffs
15 summarily cite to cases in Plaintiffs' home states where the Court recognized the
16 equitable and/or the discovery rule, yet none are class action cases where the courts in the
17 home states address the statute of limitations in connection with the predominance issue.
18 Plaintiffs simply argue that because equitable and/or the discovery rule is recognized in
19 the six sub-class states, then necessarily common proof will prevail over individual
20 questions since Plaintiffs did not know until July 11, 2016, when they received the recall
21 notices, that the INRatio Product provided erroneous readings.

22 Notably, Defendants first question whether the newly discovered evidence
23 provided in the moving papers from March 2012 would toll the statute of limitations from
24 January 2009, the date asserted in the class definition. Because certain consumer
25 protection statutes have a two year statute of limitation for breach of implied warranty
26 such as in Georgia, Ga. Code Ann. § 10-1-401, or three year statute of limitations for
27 certain New York claims, N.Y. C.P.L.R. 214(2), and three years under Colorado, Colo.

1 Rev. Stat. 13-80-101, those claims would be barred by the statute of limitations.
2 Plaintiffs do not respond to this argument.

3 Moreover, an analysis of equitable tolling and the discovery rule considers whether
4 the plaintiff acted with reasonable diligence. See e.g., Gerald v. Doran, 169 Ga. App. 22
5 (1983) (“[t]he statute of limitation is tolled until the actual fraud is discovered or by
6 reasonable diligence should have been discovered. Mere ignorance of facts constituting a
7 cause of action does not prevent the running of a statute of limitations.”); Dean Witter
8 Reynolds, Inc. v. Hartman, 911 P.2d 1094, 1096 (Colo. 1996) (the statute of limitations
9 may be equitably tolled where the defendant’s wrongful conduct prevented the plaintiff
10 from asserting his or her claims in a timely manner); Thomas v. Lopez, 982 So.2d 64, 67
11 (Fla. Dist. Ct. App. 2008) (the discovery rule in Florida establishes both a subjective
12 component, what the plaintiff actually knew, and an objective component, what an
13 objectively reasonable plaintiff should have discovered with the exercise of due
14 diligence).

15 The FAC alleges, for example, that Plaintiff Bludman suffered a TIA while riding
16 the subway in February 2016 after he had lowered his warfarin dosage to offset his high
17 INR reading. (Dkt. No. 21, FAC ¶¶ 105-06.) After returning home from the hospital,
18 Bludman began monitoring his INR with his INRatio2 testing kit and comparing those
19 results with the results of blood tests conducted by a laboratory at his hospital. (Id. ¶
20 107.) He found that his INR, using the INRatio2 testing kit, was consistently .4-.6 higher
21 than his INR, as indicated by the results of the lab tests. (Id.) This should have provided
22 Bludman with notice that there was an issue with his testing kit. Plaintiffs do not address
23 how the equitable tolling/discovery rule applies to Bludman’s situation.

24 While Plaintiffs may be entitled to tolling of the statute of limitations under
25 equitable tolling and/or the discovery rule, they have not sufficiently demonstrated its
26 application to the six sub-class states and whether these exceptions would allow the
27 statute of limitations to toll from July 2016 as to all potential class members. The Court
28 DENIES Plaintiffs’ motion for reconsideration on the statute of limitations issue.

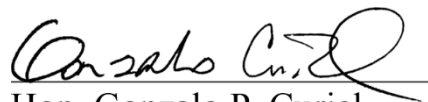
1 In sum, Plaintiffs have not carried their burden to satisfy Rule 23(b)(3)'s
2 requirement that the questions of law or fact common to the numbers of the class
3 predominate over any questions affecting only individual member on the learned
4 intermediary doctrine, Comcast damages and the statute of limitations.

5 **Conclusion**

6 Based on the above, the Court DENIES Plaintiffs' motion for reconsideration of
7 the order denying class certification. The hearing set for April 27, 2018 shall be vacated.

8 IT IS SO ORDERED.

9 Dated: April 24, 2018

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11 Hon. Gonzalo P. Curiel
12 United States District Judge
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